EXPIRED OVER-THE-COUNTER DRUG GUIDELINES
January 2012

Pursuant to Assembly Bill (AB) 688 (Chapter 681, Statutes of 2011), effective January 1, 2012, language was added to the Health and Safety Code in Part 5 of Division 104 (also known as the Sherman Food, Drug, and Cosmetic Law) commencing with Section 110286 that prohibits a retailer from selling or offering for sale any over-the-counter drug after the expiration date. In addition, language was added to the Health and Safety Code in Part 7 of Division 104 (also known as the California Retail Food Code) commencing with Section 114094.5 that prohibits a retail food facility from selling or offering for sale infant formula and baby food after the "use by" date, if a "use by" date is required by federal law.

This document was developed by the California Department of Public Health to provide guidance to industry regarding implementation and enforcement of AB 688 provisions pertaining to the retail sale of expired over-the-counter drugs.

Questions and Answers

Who is responsible for enforcing AB 688?

- The California Department of Public Health (CDPH), Food and Drug Branch (FDB), is the enforcement agency for the sale of over-the-counter drugs after the expiration date identified on the product label. Local health agencies are **not** responsible for enforcing expiration dates on over-the-counter drugs.
- Local health agencies are responsible for enforcing the "use by" dates on infant formula or baby food.

What is the definition of an over-the-counter drug?

AB 688 defines an over-the-counter drug as a nonprescription drug regulated by the federal Food and Drug Administration (FDA) that is required to have an expiration date on its packaging pursuant to Title 21 Code of Federal Regulations 211.137

What are the penalties for selling over-the-counter drugs after the expiration dates?

- The penalty for violating AB 688 is not more than ten dollars per day for each item sold or offered for sale after the expiration date. The fine shall be calculated based upon the number of days past the expiration date that the product is found being offered for sale. CDPH may also assess administrative penalties of ten dollars per day for each item sold or offered for sale after the expiration date
- The above penalties can be assessed in addition to other penalties authorized by law.
- The assessment of penalties allowed by AB 688 is at the discretion of CDPH.

Will a sales receipt be used solely to determine a violation?

- A sales receipt should not be used solely to determine a violation. There is no mechanism to connect the sale of an over-the-counter drug identified on a receipt with a specific product container.

How will local CDPH enforce AB 688?

- AB 688 does not require CDPH to conduct regular or routine inspections of retail facilities where over-the-counter drugs are sold.
- CDPH will respond to complaints from consumers and industry where the sale of expired over-the-counter drugs is alleged to be occurring at retail locations in California.

Will there be an investigation for each complaint?

- CDPH has the discretion to respond to complaints in a variety of ways, none of which require each complaint be addressed individually.
- CDPH will consider the volume of complaints or a pattern of complaints for a specific retailer before initiating enforcement.

How will compliance be assessed in complaint investigations?

- Compliance with AB 688 may be checked by inspecting the expiration date on covered products which are being offered for sale to the consumer.
- Federal law allows manufacturers to include only the expiration month and year on over-the-counter drug product labels. For the purposes of determining expiration date, the product is considered expired on the last day of the month in the year indicated on the product label.